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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,966	05/01/2002	Masataka Nadaoka	2001-1915A	6249

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,966	NADAOKA ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/24/05*. k 12/04/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 April 2005 has been entered.

2. Claims 1-27 have been canceled. Claims 28-33 have been entered and are pending.

3. The text of those US codes not found in this office action may be found in a previous office action.

Claim Rejections - 35 USC § 112

4. Claims 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is vague and indefinite because the relationship between the components in the inspection target solution and the marker reagent has not been properly defined. Even though the claim recites that the marker reagent can be bonded to the measurement target (i.e. analyte), it is unclear if this complex then binds to the immobilized reagent forming a sandwich of sort. The relationship between the marker

reagent and the immobilized reagent is also vague. The immobilized reagent is recited as either binding to the analyte, OR binding to the marker reagent; however, it is unclear if the marker reagent and the analyte competes for binding to the immobilized

Claim 28 is further confusing because there are two separate measuring steps that do not appear to relate to each other. The step of measuring *between* said first and second parts of the development portion is confusing since it is unclear how the amount of marker reagent in between the two parts relates to the amount of analyte in the sample.

Because the binding relationship between the various reagents are unclear, it is confusing how the measurement of marker reagent that is bound to the immobilized reagent can reflects the quality or quantity of analyte. The presentation of multiple alternative embodiments is confusing because it is unclear which of these limitations belong with one another.

Claim 28 recites a step of correcting the measured bonding amount of the marker reagent on the basis of the amount of marker reagent eluted from the development portion but are not immobilized in the second part of the development portion. However, it is unclear what exactly is involved in this correction? Is a ratio being taken, a difference or a total of the marker reagent?

Claims 28-33 are vague and indefinite with respect to the recitation of the marker reagent that has been eluted from said first part of the development portion because it is unclear if this includes those that have been immobilized in the second part of the

development portion. The recitation that the eluted marker reagent (if any) is measured *between* said first and second parts of the development portion is confusing because it is unclear how this eluted marker reagent (a moving component) is measured?

Claim 29 is further confusing because it is recited in part (ii) that the marker reagent is eluted from the first region when liquid sample is applied thereto; however, part (2) of the claim recites a measurement step where marker reagent that has not been eluted from said first region is measured. These two steps appear to contradict each other.

Response to Arguments

5. Applicant's arguments filed 21 March 2005 have been fully considered but they are not persuasive.

Applicant asserts that new claims 28 and 29 addressed the 112, 2nd paragraph rejection of record; however, these claims are still confusing as stated above.

Specifically, even though the marker reagent is recited as binding to the analyte, it is also alternatively recited as binding to the immobilized reagent. This, in itself, is proper. However, when combined with the alternative embodiments of the immobilized reagent and the measuring steps, it is confusing.

For example, when the analyte binds to the marker reagent, does this complex bind the immobilized reagent? This is not clear.

Alternatively, when the marker reagent binds to the immobilized reagent, how is this related to the analyte, is there competition between the marker reagent and the analyte for binding to the immobilized reagent? This is not clear.

In the event that the marker reagent binds to the analyte but the complex does not bind to the immobilized reagent, the step where the amount of marker reagent that is bound to the immobilized reagent is measured to obtain the amount of analyte is confusing because it relationship is unclear.

Applicant asserts that the "correcting step" is clear; however, this is not persuasive. As stated previously, what exactly does "on the basis of the amount" means? Do you take the difference between the eluted marker in the first part and the bound marker in the second part? Do you take the sum? Do you take the ratio?

Applicant asserts that there is a measurement of the marker reagent that takes place between the first and second part of the development portion. This is confusing because both claims 28 and 29 recite that the marker reagent is in elutable form on the first part, and is in fact, eluted when liquid sample is applied thereto. Thus, this measurement step serves no purpose since the amount of marker reagent applied to the first part is presumably known, it is expected that all of the marker reagent will be eluted from the first part. Applicant does not make a distinction between those that are found to the analyte and those that are unbound to the analyte.

It appears that there is some sort of baseline reading but because the claims are vague, it cannot be determined exactly what is take place.

It is recommended that applicant positively recited each and every element of the device being used, as well as each and every step of the method.

Claim Rejections - 35 USC § 102

6. Claims 28-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DeLaCroix et al (US 5,206,177).

DeLaCroix discloses a device and method for detecting analytes from a sample comprising means for separating mobile detectable moiety from unreacted components. The device comprises an optional sponge 13 which can be impregnated with a buffer, and may receive the sample being analyzed. The first zone 14 is positioned so that it receives sample which diffuses from sponge 13 when the sponge is used. Zone 14 contains a conjugate pad 15, and a matrix 16. Conjugate pad 15 contains the removable labeled analyte, labeled analyte analogue, or labeled binding partner. When the sample contacts this region, either by direct contact or by diffusion, the conjugate and the sample mixes, and any reactions between analyte and binding partner takes place. The mixture passes to matrix 16, which contains an immobilized form of a reagent. Generally the immobilized reagent is identical, or epitopically equivalent to the analyte being determined. When this is the case, the immobilized reagent must be present in an amount sufficient to bind essentially all of the labeled conjugate present in conjugate pad 15. This is necessary to provide for the situation where the sample contains none of the analyte being determined. In a displacement assay, conjugate pad 15 and matrix 16

will be of one piece because the immobilized reagent will already have bound to it the labeled analyte or analyte analogue. Second zone 19 contains two parts, but this is not necessarily so. Substrate pad 18 contains a substrate which reacts with the label on the labeled component to form a detectable signal. This may be, but need not be, an enzyme substrate. Trapper pad 20 is in fluid contact with the substrate pad 18, or, if 18 and 20 constitute one piece, this one-piece second zone is in fluid contact with the first zone. The trapper pad 20 contains a means, such as ionic exchange paper, which traps either the reaction product of the label and substrate, or unreacted substrate. Finally, in fluid contact with the second zone 19 is the waste pad 22, which is adapted for receiving excess fluid. Further, it absorbs any materials which may be removed when the test strip is washed. The waste pad 22 can, alternatively, be used as a measuring point. When separation of detectable moiety and unreacted reaction component takes place in the second zone 19, the element which is not trapped can be washed into the waste pad. This element, rather than the trapped element, can be measured as well as, or in preference to, the trapped element. See column 6, line 12 through column 7, line 9.

Even though DeLaCroix does not specifically recite correcting the measured amount of marker reagent in the detection zone, DeLaCroix is seen to anticipates the instant invention because the correcting step recited in the claim appears to be nothing more than taking an additional measurement of the marker reagent in another zone or those that are unreacted, both of these steps are taught by DeLaCroix.

7. Claims 28-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuo (EP 0 895 084 A2).

Kuo discloses a method and device for determination of an analyte in a sample of body fluid. The test strip comprises a matrix made of paper, nitrocellulose or nylon material (page 3, lines 43-50). The strip has a first region which contains mobile specific binding partner for the analyte which bears a detectable label such as gold sol or latex particles; a second region containing immobilized binding partner which is specific for an epitope of the analyte different than that to which analyte binding gold sol particles are specific; and a third region containing means for capturing the analyte/labeled specific binding partner complex which is not bound in the second region (page 2, line 55 through page 3, line6). The third region may also contain an immobilized antibody against the labeled binding partner (e.g. anti-mouse IgG when the labeled binding partner is an antibody). See page 4, lines 7-12. Kuo also teaches an absorbent pad which serves to absorb the liquid that migrates pass the various zones of the test strip (page 7, lines 56-57). In use, sample is applied to the test strip at an application point, (area 1 of figure 1) and allowed to migrate to the various zones of the test strip. Signals from the detectable label in the second region (sample capture zone) and from the detectable label in the third region (control capture zone) are measured using an optical detector (page 2, lines 19-20), and the ratios of these signals is determined and related to the amount of the analyte in the sample. Kuo teaches that such a determination provides the advantage of an increase in accuracies, because it corrects for inaccuracies

in labeled conjugate deposition and/or non-uniform flow through the matrix (page 4, lines 6-17). Kuo also teaches a method in which the summation of the signal from both the sample capture and control capture zones is taken, and the ratio of the signal in the sample capture zone and the sum is used to determine the amount of analyte (page 4, lines 34-37). Kuo teaches that the test strip and method disclosed may be adapted to determine various types of analytes such as PSA and hCG (page 7, lines 13-21) in body samples such as serum.

Response to Arguments

8. Applicant's arguments filed 27 October 2004 have been fully considered but they are not persuasive.

Applicant argues that DeLaCroix does not disclose that a measurement value of the element which is trapped by the trapper pad 20 is "corrected" by a measurement value of the element which is not trapped. Thus, DeLaCroix does not anticipate the pending claims.

While it may be true that DeLaCroix does not specifically recite a correcting step, it is also true that the pending claims do not clearly state how the correcting step is performed. As stated above, the correcting step is nothing more than taking a measurement of unreacted marker reagents and a measurement of marker reagents in a zone that this different from the detection zone. Both of these measurement steps are

taught by DeLaCroix, therefore, DeLaCroix anticipates, or in the alternative, makes obvious the instant claims.

Applicant argues that Kuo does not teach measuring the amount of the marker reagent that has been eluted or the amount of the marker that has not been eluted upstream of the immobilized reagent.

This argument is not persuasive. *The immobilized reagent* in the instant invention is seen to be the same as the means located in the third region of the test strip for capturing the analyte/labeled specific binding partner complex. In this instant, Kou does teach the measurement of elutable marker reagent upstream of the immozilibed reagent because Kuo teaches measuring marker reagent that may be captured in a second region of the test strip, i.e. those that has eluted from their original location. See page 3, lines 1-6.

Applicant argues that Kuo does not teach that the measurement value used for correction is measured in a region upstream of the immobilized reagent. This argument is not persuasive for the reason stated above. Kou teaches that a final response signal is obtain by ratioing the signals from the marker reagent in the second region (upstream of the immobilized reagent) and the signal from the labeled binding partner capture in the third region (i.e. the immobilized reagent). See page 3, lines 24-25. This step is seen to be the same with the instant correcting step. The fact that Kuo also teaches other correction step is irrelevant since the instant claims do not limit these additional steps.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,451,504

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
6/23/05